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(54) Hydraulic pump

(57) A hydraulic pump, having an infusion set (12) adapted to serve as drive liquid for the pump, hydraulic actuator (2), connected to infusion set (12), and comprising, in one embodiment, a piston (6) which is acted upon by the drive liquid (8) to advance plunger rod (28) and, to expel the infusion liquid (40) from the syringe (25) towards the recipient. Other embodiments are disclosed in which the piston (6) and syringe (25) are replaced.

Fig. 1.

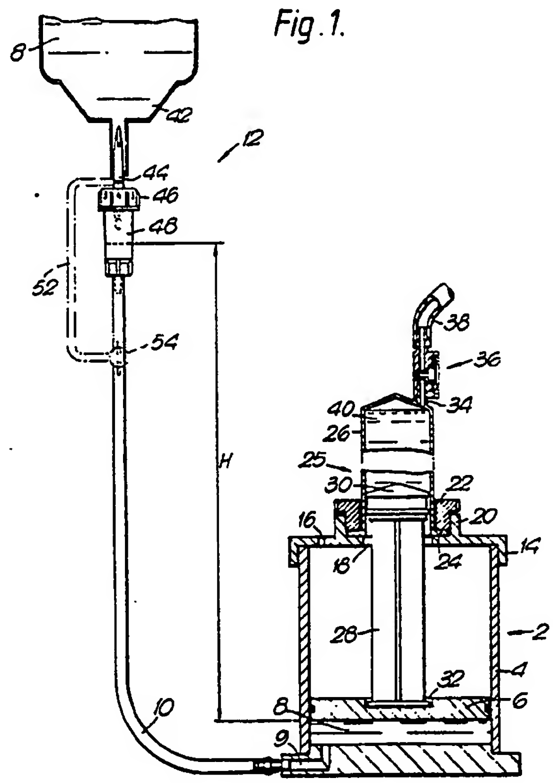

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Fig.1.

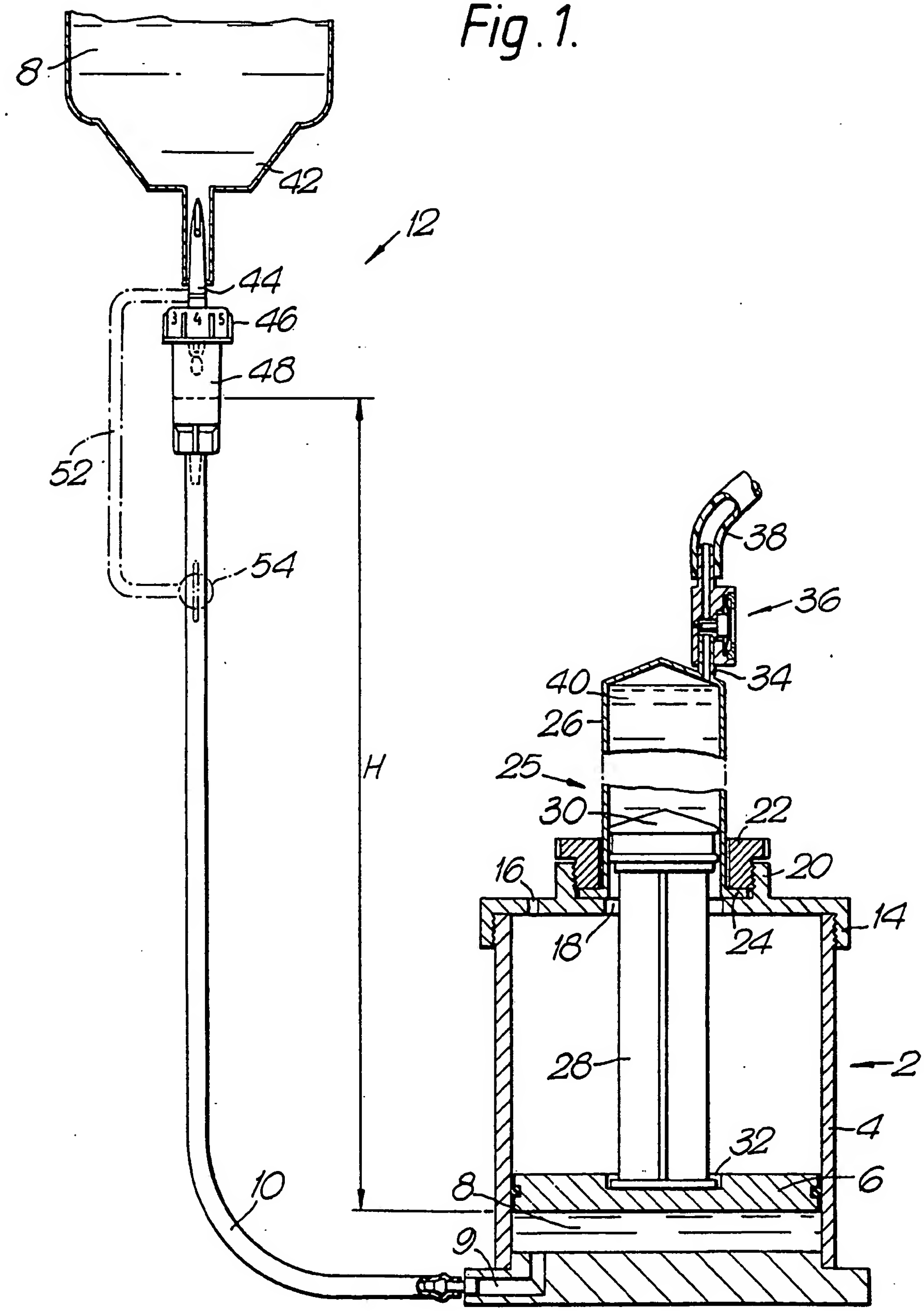
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Fig. 2.

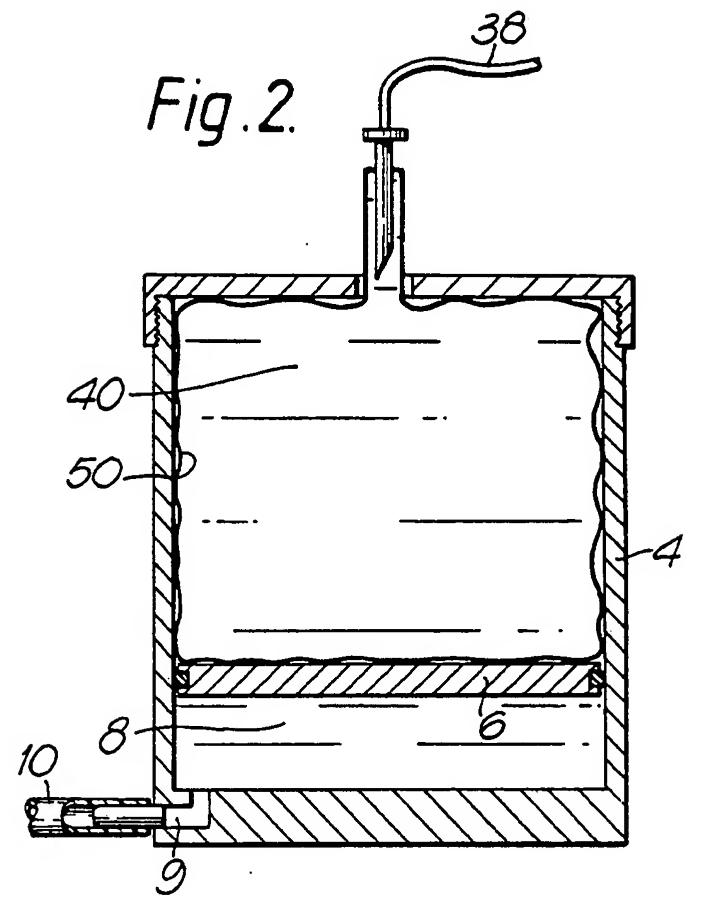

Fig. 3.

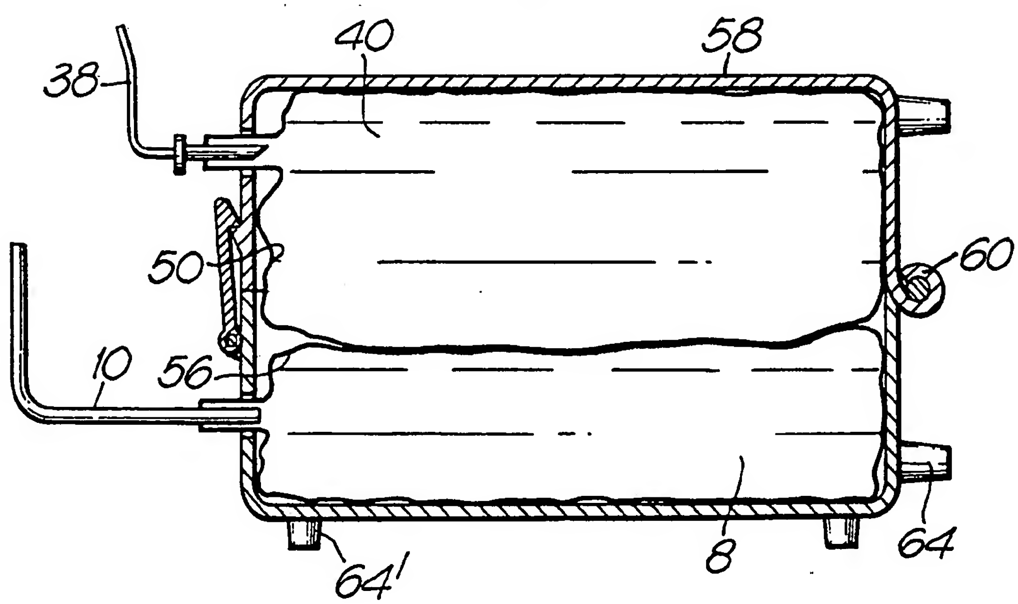

Fig. 4.

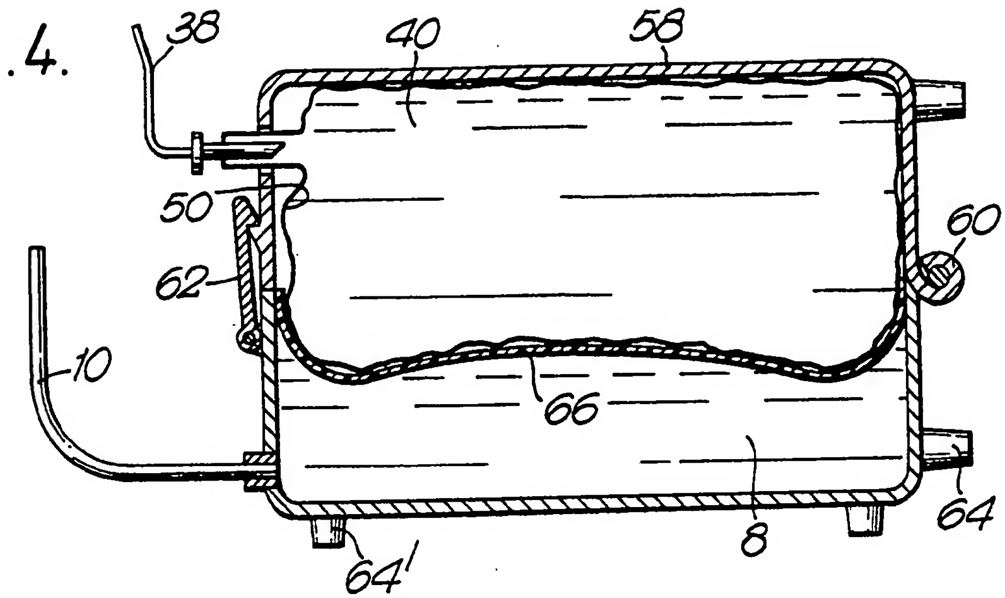
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Fig. 5.

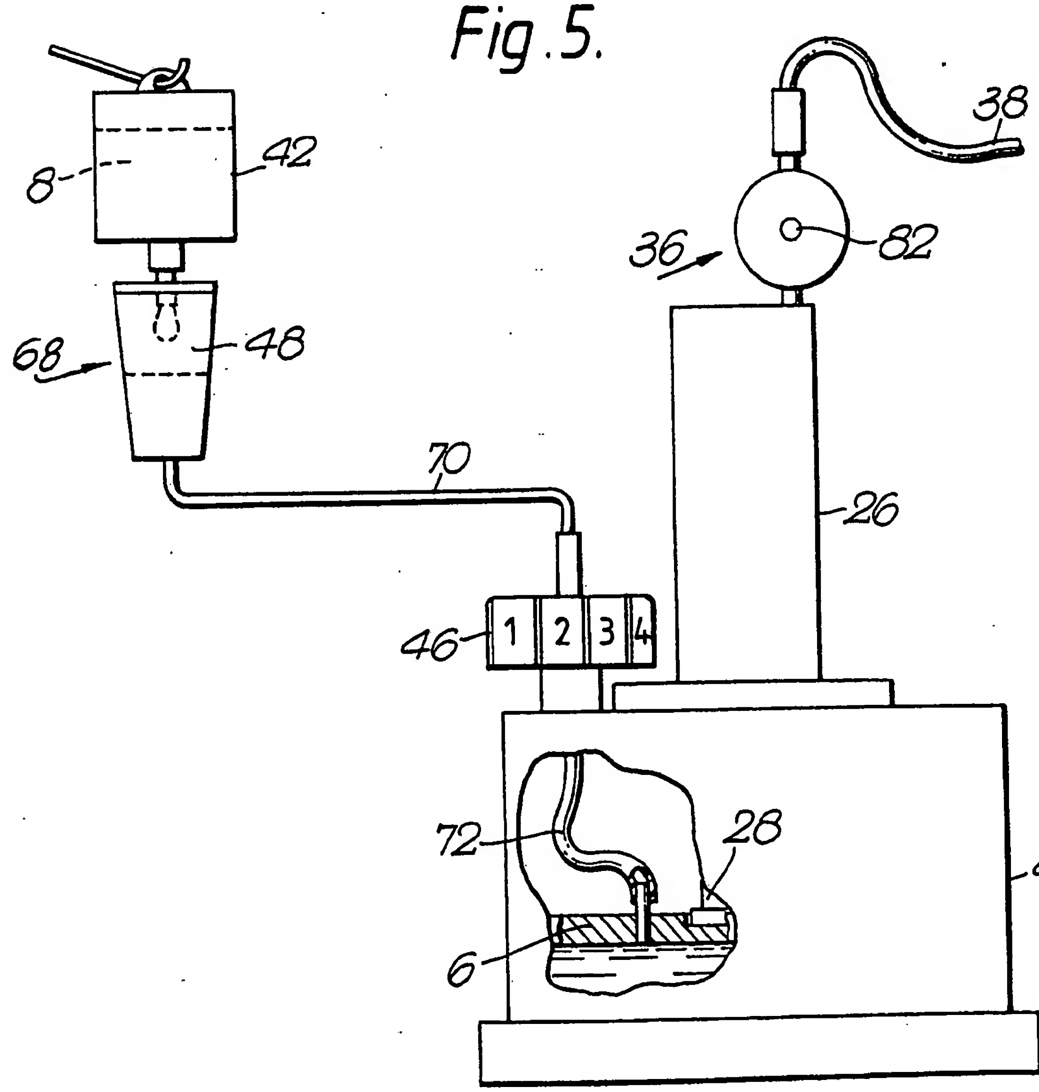
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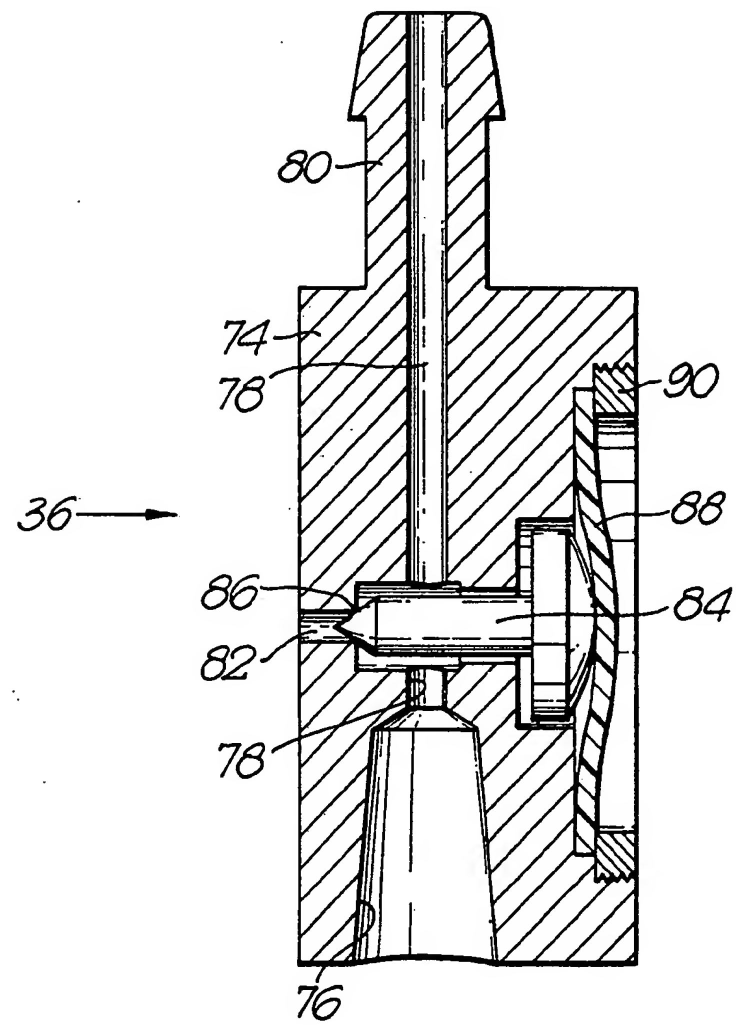
Fig.6.



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HYDRAULIC SYRINGE PUMP

The present invention relates to a hydraulic syringe pump.

While conventional infusion sets give reliable service for infusion rates as low as 4 drops/min, intravenous administration of certain drugs such as insulin in critical diabetes applications, antiarrhythmics, anticoagulants, vasodilators and others, requires infusion rates lower by one or even two orders of magnitude than those achievable with ordinary infusion sets. Today, this range is covered by so-called syringe pumps which consist of syringes the plungers of which are advanced at presettable rates by means of micrometric screws (or by cams) driven by electronically controlled stepping or gear motors.

These pumps, while usually giving satisfactory service, are, however, relatively very expensive.

It is one of the objects of the present invention to provide a syringe pump that, while being not less accurate and reliable than the above-mentioned syringe pumps, is much less expensive and operates without line or battery power.

This the invention achieves by providing a hydraulic syringe pump, comprising:

means adapted to produce a constant, adjustable and quantifiable flow of liquid to serve as drive liquid for said pump;

hydraulic actuator means, connectable to said drive-liquid-flow producing means and comprising at least one member adapted to be acted upon by an inflow of said drive liquid and, in response to said inflow, to produce a movement, and

variable-volume means containing an infusion liquid and adapted to be acted upon by said movement-producing member and, in response thereto, to progressively expel said infusion liquid from said means towards the recipient thereof.

The invention will now be described in connection with certain preferred embodiments with reference to the following illustrative figures so that it may be more fully understood.

With specific reference now to the figures in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

Fig. 1 is a view, partly in cross section, of a first embodiment of the hydraulic syringe pump according to the invention;

Fig. 2 is a schematic cross-sectional view of the hydraulic actuator of a second embodiment of the invention, in which the syringe is replaced by a plastic bag;

Fig. 3 shows a schematic, cross-sectional view of a further embodiment in which both the syringe and the piston have been replaced by plastic bags;

Fig. 4 represents a variant of the embodiment of Fig. 3, in which the drive liquid acts upon the infusion-liquid bag via a diaphragm;

Fig. 5 illustrates the use, with the embodiment of Fig. 1, of a standard, nonregulated infusion set, and

Fig. 6 is a view, in cross section, of the pressure relief valve.

Referring now to the drawings, there is seen in Fig. 1 a hydraulic actuator 2 in the form of a hydraulic cylinder 4 in which is slidably arranged a piston 6. The cylinder portion below the piston 6 is accessible to the drive liquid 8 of the device by being connected, via a passageway 9 and a tube 10, to means 12, described in detail further below, adapted to produce a constant, adjustable and quantifiable flow of liquid to serve as the above-mentioned drive liquid which, when entering the cylinder 4 through the passageway 9, will clearly cause the piston 6 to rise. The cylinder 4 is covered by a

lid 14 provided with an air vent 16, a central bore 18 and a collar 20 with an internal thread.

Inside the collar 20, clamped by a threaded ring 22 against the lid 14, is seated the gripping flange 24 of a syringe 25 preferably of the disposable type.

The syringe body 26 is thus immobilized relative to the cylinder 4.

The plunger rod 28 which, in these syringes, is integral with the syringe plunger 30, rests on the bottom of, and is centered inside, a recess 32 on the top surface of the piston 6 of the hydraulic cylinder 4. On the standard taper 34 of the syringe outlet is mounted a pressure relief valve 36 the function of which is to prevent formation of excessive pressure which may occur, e.g., due to occlusion in the perfused vein. The functioning and structure of this valve will be explained further below in conjunction with Fig. 6. The tube 38 attached to the output side of the valve 36 leads to the patient. The infusion liquid 40 is clearly contained in the syringe body 26.

The drive liquid 8, on the other hand, i.e., the liquid that, entering the cylinder through the passageway 9, causes the piston 6 to move, has its origin in what will be immediately recognized as the bag

42 of an infusion set, earlier described as "means 12 adapted to produce a constant, adjustable and quantifiable flow of liquid."

This set (the term "infusion" now no longer denotes its present use, only its antecedents) is in this embodiment of the "regulated" type, i.e., once set to a certain dripping rate, it practically maintains that rate in spite of the falling liquid level in the bag. It is seen to comprise the pointed snout 44, pushed into the bag 42, the regulating member 46, in most models provided with a scale, and the transparent drip chamber 48 which permits the dripping action to be verified as well as quantified, (e.g., by counting the drops per unit time).

The bag 42, as stated earlier, now contains the working or drive liquid 8 and is hung on a stand at some height above the syringe pump 2, so that a height difference, or head, H is produced between the liquid level in the dripping chamber 48 and the level in the cylinder 4. It is due to this head H that a considerable hydrostatic force is exerted on the lower piston surface, a force that equals the height H times the surface area A of the piston times the specific weight of the liquid and, it will be remembered, is quite independent of the diameter of the tube 10 or the actual amount of liquid in that tube.

It will now be understood that the mere presence of a head H will cause the piston 6 to be forced upwards, each drop raising the piston

6 by a distance Δh equal to the volume V of the drop divided by the surface area A of the piston 6. Now whatever the amount of rise Δh per drop of driving liquid, it is obvious that the plunger rod 28 and, consequently, the syringe plunger 30, will be pushed up by the same amount Δh. It is also clear that the volume v of infusion liquid expelled from the syringe 25 when the plunger 30 advances by a distance Δh, equals $v = \Delta h \times a$, where a is the surface area of the plunger 30, and since $a<A$, the output v of infusion liquid 40 per plunger diplacement Δh will be much smaller than the volume V of a drive liquid drop which produced that displacement Δh. In fact, $v:V = a:A$ and, therefore, $v = Va/A$. The fraction a/A is thus the dimensionless reduction ratio which, multiplied with the drop rate of the drive liquid in the "infusion" set (drops/min) will give the equivalent drop rate of the infusion liquid. The "equivalent" infusion drop rate refers to the number of infusion drops per unit time obtained if the separate "spurts" of infusion liquid issuing from the syringe 25 were to consolidate into drops of the volume of the drive liquid drops. This volume is standardized with most infusion sets - being 0.05 cc per drop of liquid having a viscosity similar to that of physiological liquids - and, in any case, can be ascertained by simple measurement. Clearly this reduction ratio will be the larger, the smaller the plunger diameter of the syringe used. Thus a standard 60 cc syringe used with a cylinder 4 of a diameter of about 9 cm will give a reduction ratio of 1:10, while the same cylinder used in conjunction with a 1 cc syringe will produce a reduction ratio of about 1:350. By

way of example, using a 60 cc syringe, i.e., a reduction ratio of 1:10 (=0.1), a drive liquid drop rate of 4/min will result in an equivalent infusion liquid drop rate of 4x0.1 = 0.4. Conversely, if, at this reduction ratio, an equivalent infusion-liquid drop rate of, e.g., 0.5/min was required, the drive liquid drop rate to be set on the scale would be 0.5/0.1 = 5 drops/min.

The drive liquid to be used with the above-discussed embodiment is optional, as long as its viscosity is in the range of viscosity of physiological liquids such as blood, plasma, saline, etc., for which the scale 46 of the set is calibrated. A preferred drive liquid would be distilled water which will leave no residues.

In order to prepare the syringe pump according to the invention for another infusion round, the cylinder 4 must be emptied of drive liquid 8, before a new (and full) syringe 25 can be installed. The drive liquid 8 can be either discarded, for which purpose a drain cock is provided (not shown), or the liquid is returned to the bag 42 by setting the scale 46, to "priming", which causes the flow-restricting path in the set to be bypassed. The set, including the bag 42, is then lowered to a level below the cylinder 4, which will cause the liquid 8 to return to the bag within a short time. External bypass alternatives will be discussed further below.

In the embodiment shown in Fig. 2, the disposable syringe 25 has been replaced by a plastic infusion-liquid bag 50 which, at the beginning of an infusion round, completely fills the cylinder space above the piston 6 (which is of course at its lowermost position).

According to the hydrostatics of this arrangement, there is no reduction ratio in the sense of the embodiment of Fig. 1, as there is no longer any difference in the respective cross-sectional areas. Thus, the volume of infusion liquid squirted out of the bag 50 for each drop of drive liquid 8 entering the cylinder 4 will be exactly equal to the volume of this drop. Here, a reduction in the above-mentioned minimum, still controllable drop rate of 4 drops/min is obtained by using drive liquids such as various types of oils, the viscosities of which are much higher than that of the usual physiological liquids. Using such oils with standard or regulated infusion sets, it is possible to attain drop rates 10 to 100 times lower than those obtainable with standard infusion liquids.

The rest of the setup - "infusion" set, tube connection - is identical to that shown in Fig. 1, except that, because of the nature of the drive liquid, it is advantageous to provide an exterior, larger-bore bypass 52 (see Fig. 1), one end of which connects into the snout 44, and the other end into a 3-way cock 54 which, in the position shown, cuts off the bypass 52, and establishes a direct connection between the set and the cylinder 4, and, being turned 90°,

permits the oil being returned from the cylinder 4 to the bag 42, to bypass the set for rapid emptying of the cylinder 4. With another solution, the 3-way cock 54 is dispensed with by providing a nonreturn valve which permits the drive liquid to flow from the cylinder 4 back to the bag 42, but prevents its flow from the bag 42 into the cylinder.

The pressure relief valve 36 of Fig. 1 is not needed in the embodiments of Figs. 2-5, as pressures in these embodiments, even at total occlusion, can never reach the dangerous level of, say, 300 mm Hg.

Fig. 3 illustrates an embodiment in which both the syringe 25 and the piston 6 have been replaced by plastic receptacles, the former by a plastic bag 50 similar to that of the embodiment of Fig. 2, and the latter by a hydraulic cushion 56 made of an elastically deformable material and connectable via the tube 10 to the drive-liquid dispensing set 12. Both the bag 50 and the cushion 56 are accommodated in a rigid two-part housing 58 the two halves of which are articulated to one another by means of a hinge 60 and can be maintained in the closed position with the aid of a latch 62.

Operation of this embodiment is quite obvious. In the beginning, the hydraulic cushion 56 is fully collapsed and the infusion-liquid bag 50 fills the entire housing. With infusion in progress, the

hydraulic cushion slowly fills and, at the same rate, expels infusion liquid 40 from bag 50 into the infusion line 38, the sum of the respective liquid volumes of the drive-liquid hydraulic cushion 56 and the infusion-liquid bag 50 remaining substantially constant, equalling the inside volume of the housing.

This embodiment, too, has no reduction ratio in the sense of the embodiment of Fig. 1, and drop rates lower than the minimum drop rate of standard or regulated infusion sets are obtained by using as a drive liquid a liquid of relatively high viscosity.

The housing has two sets of legs 64, 64', which give it two possible positions, upright and flat. The upright position is more advantageous during the priming stage, where all air must be eliminated, especially from the infusion-liquid bag 50.

A variant of the embodiment of Fig. 3 is shown in Fig. 4. In this variant the hydraulic cushion 56 which was progressively inflated by the drive liquid, is replaced by an elastically deformable diaphragm 66. Here, the drive liquid 8 is introduced into the housing 58 and progressively forces the diaphragm 66 against the infusion-liquid bag 66. Here, too, drop rates are lowered by the use of high-viscosity liquids as drive liquids.

Fig. 5 illustrates the use, in a variant of the embodiment of Fig. 1, of a nonregulated standard infusion set 68. Here, the regulator 46 is a separate component of the in-line type and connected to the drip chamber 48 by a flexible tube 70, and to the cylinder space below the piston 6 by another flexible tube 72. It is, of course, also possible to effect regulation by means of the simple, well-known devices which are often used with the standard infusion set, namely the roller clamp or the flat clamp. Both are meant to be applied to the outlet tube of the infusion set, and reduce the free cross section of this tube by flattening it to a greater or lesser degree. The reliability and accuracy of these clamps are, however, rather limited.

Fig. 6 shows the pressure relief valve 36. There is seen the valve body 74 having an inlet opening 76 which is tapered to fit the standard taper of the syringe 25 (Fig. 1). A smaller, cylindrical bore 78 leads from the end of the tapered inlet through the body 74 to the tube connector 80 over which is pushed the infusion line 38 leading to the patient. A venting hole 82 is, in operation, kept close by a poppet valve 84 having a tapered end and pressed against the valve seat 86 by the elastic force of a rubber diaphragm 88 held in position by a threaded retaining ring 90. The diaphragm 88 senses the pressure in the bore 78 and, when a certain limit pressure is exceeded, bulges outwardly. This allows the poppet valve 84 to retreat, which causes the tapered end thereof to be lifted off the

valve seat 86, permitting the infusion liquid to escape through the venting hole 82. When pressure returns to normal, the elastic force of the diaphragm 88 will push the poppet valve 84 back, until its point again obturates the vent 82. It is also possible to make the poppet valve 84 an integral part of the diaphragm 88.

While the embodiment of Fig. 1 has been shown as having one syringe only, it is obviously possible to provide more than one syringe, for instance two, having different diameters and being actuated simultaneously. This would increase the variability of the infusion rates obtainable.

It is also possible to replace the piston 6 of Fig. 1 by a bellows arrangement or by a rolling diaphragm, either of which would substantially reduce friction and increase smoothness of action as well as accuracy.

It will be evident to those skilled in the art that the invention is not limited to the details of the foregoing illustrative embodiments and that the present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning

and range of equivalency of the claims are therefore intended to be embraced therein.

CLAIMS

1. A hydraulic syringe pump, comprising:

means adapted to produce a constant, adjustable and quantifiable flow of liquid to serve as drive liquid for said pump;

hydraulic actuator means, connectable to said drive-liquid-flow producing means and comprising at least one member adapted to be acted upon by an inflow of said drive liquid and, in response to said inflow, to produce a movement, and

variable-volume means containing an infusion liquid and adapted to be acted upon by said movement-producing member and, in response thereto, to progressively expel said infusion liquid from said means towards the recipient thereof.

2. The syringe pump as claimed in claim 1, wherein said drive-liquid-flow producing means is an infusion set.

3. The syringe pump as claimed in claim 2, further comprising flow-regulation means interposed between said infusion set and said hydraulic actuator means.

4. The syringe pump as claimed in claim 1, wherein said drive-liquid-flow producing means is a regulated infusion set.

5. The syringe pump as claimed in claim 1, wherein said hydraulic actuator is a hydraulic cylinder, and wherein said member is the piston of said cylinder, one surface of which piston is accessible to said drive liquid.

6. The syringe pump as claimed in claim 5, wherein said variable-volume means is a syringe containing an infusion liquid to be administered, the body portion of which syringe is stationery relative to said cylinder and the plunger rod of which rests against the other piston surface, the surface area of said piston being substantially larger than the surface area of the plunger of said syringe, wherein said piston, moving in response to said inflow, pushes said syringe plunger into said syringe body, thereby expelling said infusion liquid through the outlet opening of said syringe.

7. The syringe pump as claimed in claim 5, wherein said drive-liquid flow-producing means is located at such a height above said cylinder as to produce an appreciable pressure head acting on said piston surface.

8. The syringe pump as claimed in claim 1, further comprising a pressure relief valve interposed between said variable-volume means and the recipient of said infusion liquid.

9. The syringe pump as claimed in claim 5, wherein said variable-volume means containing said infusion liquid is a collapsible bag insertible into said cylinder and substantially filling the space above said piston, which bag is provided with an opening connectable to the recipient of said infusion liquid.

10. The syring pump as claimed in claim 1, wherein said actuator means is a hydraulic cushion connectable to said drive-liquid-flow producing means and accommodated in a rigid housing.

11. The syringe pump as claimed in claim 10, wherein said variable-volume means containing said infusion liquid is a collapsible bag insertible into said rigid housing and being provided with an opening connectable to the recipient of said infusion liquid; said bag sharing said housing with said hydraulic cusion connectable to said drive-liquid-flow producing means, wherein during operation the sum of the respective liquid volumes of said hydraulic cushion and said infusion liquid bag remains substantially constant, being substantialy equal to the inside volume of said rigid housing.

12. The syringe pump as claimed in claim 11, wherein said hydraulic actuator means is an elastically deformable diaphragm sharing a rigid housing with said collapsible infusion-liquid bag, and mounted in said housing in such a way as to be exposed, on one of its surfaces, to the

inflow of said drive liquid, and to be pressable against said infusion-liquid bag with the other one of said surfaces.

13. The syringe pump as claimed in claim 1, further comprising means for bypassing said means producing said drive-liquid flow, said bypassing means being adaptd to prevent said drive liquid from bypassing said flow-producing means in direction towards said hydraulic actuator means, but permitting said drive liquid to bypass said flow-producing means when coming from said hydraulic actuator means.

14. The syringe pump as claimed in claim 1, wherein said drive liquid is a liquid having a viscosity substantially within the range of viscosities of physiological liquids.

15. The syringe pump as claimed in claim 1, wherein said drive liquid is a liquid having a viscosity substantially above the range of viscosities of physiological liquids.

16. The syringe pump as claimed in claim 1 and substantially as hereinbefore described with reference to the accompanying drawings.